K003275

APR 2 3 2001

Synthes Spine 510(k) Premarket Notification
Synthes SynMesh™ Spacer

Summary of Safety and Effectiveness Information

SPONSOR:

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700
Contact: Jonathan Gilbert

DEVICE NAME:

Synthes SynMesh™ Spacer System

CLASSIFICATION:

Per CFR 21, §888.3060: Implant, fixation, spinal intervertebral body fixation orthosis devices. Class II.
Product code is MQP. The Panel code is 87.

PREDICATE DEVICE:

Depuy AcroMed Stackable Cage System - K001340 - K990148

DEVICE DESCRIPTION:

The design of the SynMesh™ Spacer implant includes cylindrical meshes with either round or oblong mesh cross-section, end rings, standard rings and screws.

The end rings for the round or oblong mesh share the same cross sectional diameters as their corresponding mesh cross-section and are either a flat or angled. The end rings are manually pressed into the ends of the mesh, or may be affixed with screws, and are intended to help restore the natural curvature of the spine. Teeth on the end ring surfaces help prevent lateral movement of the device. There is a central opening in the end ring that allows contact between the contents of the mesh and the endplates of the adjacent vertebral body.

Standard rings are available for use with the oblong mesh. Two screws affix the standard ring to the mesh. The standard ring is used only for additional circumferential hoop strength at the discretion of the surgeon.

The interior of the mesh is open and is filled with bone graft material. The SynMesh™ Spacer cylinders may be used singly or in pairs (circular mesh is always used in pairs), depending on the surgical need, however the device is always implanted with the mesh oriented vertically.

INTENDED USE:

The SynMesh™ Spacer System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable

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Synthes SynMesh™ Spacer

vertebral body due to tumor or trauma (i.e., fracture). The SynMesh™ Spacer System is intended to be used with Synthes supplemental internal fixation systems, e.g., ATLP, VentroFix and USS. The interior of the spacer component of the SynMesh™ Spacer System can be packed with bone.

The SynMesh™ Spacer System is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

MATERIAL: All mesh components of the SynMesh™ Spacer are manufactured from commercially pure titanium. (ASTM F67) or titanium alloy Ti6Al7Nb (ASTM F1295).

PERFORMANCE DATA: Mechanical testing (ASTM F1717-96) was presented.

BASIS OF SUBSTANTIAL EQUIVALENCE: The Synthes SynMesh™ Spacer implants are similar to the components of previously cleared spinal systems (K990148 & K001340). The supplemental fixation devices intended for use with the Synthes SynMesh™ Spacer are currently cleared for use in patients with either tumor, trauma or fractures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2001

Mr. Jonathan Gilbert
Senior RA Associate
Synthes Spine
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301-1262

Re: K003275
Trade Name: SynMesh™ Spacer System
Product Code: MQP
Regulatory Class: II
Dated: January 22, 2001
Received: January 23, 2001

Dear Mr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Synthes Spine 510(k) Premarket Notification
Synthes SynMesh™ Spacer

Indications for Use Statement

510(k) Number (if known): K003275

Device Name: Synthes SynMesh™ Spacer

INDICATIONS:

The SynMesh™ Spacer System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The SynMesh™ Spacer System is intended to be used with Synthes supplemental internal fixation systems, e.g., ATLP, VentroFix and USS. The interior of the spacer component of the SynMesh™ Spacer System can be packed with bone.

The SynMesh™ Spacer System is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003275